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Biosecurity:
How COVID-19 is a Warning to Prepare Against Future Biological Threats

PERSPECTIVE

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In this Report

The COVID-19 pandemic hit the world quickly following its discovery in late 2019. At the time of this publication, the disease has infected more than 615 million people worldwide and caused more than 6.5 million deaths. The full effects of the pandemic and its impact on history won't be clear for years, but one thing that is clear now is that things could have been much worse. The COVID-19 pandemic has spurred a renewed interest in global health security, and one of the core components to global health security considerations in capitals worldwide should be better understanding how technological advancement, such as genetic engineering, could exacerbate the already fragile global health security environment. This report puts forth several suggestions on ways the United States can improve national and international biosecurity.

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IN BRIEF

- The COVID-19 pandemic has shown how infectious disease outbreaks can have severe effects on economics and security in states worldwide. It will likely take years to fully understand the effects of COVID-19, but its already clear the outbreak could have been much worse.
- Synthetic biology and scientific advancement have made it clear that barriers to entry in designing infectious diseases to be biological weapons is easier than ever and a real threat to international security.
- To improve biosecurity at a national and international level, the U.S. should consider taking the lead on revamping international biosecurity practices, establishing controls on emerging technology, maintain national preparedness, and centralize community responses to infectious disease outbreaks.

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Introduction

The SARS-CoV-2 virus, better known as COVID-19, rocked the world as it rapidly spread across the globe following its emergence in December 2019. Despite the incredible scientific accomplishment of rapid vaccine development, the virus continued to take a toll on the global population through 2021 and into 2022. As of early October 2022, total COVID cases hit more than 615 million with more than 6.5 million deaths, including more than 96 million cases and one million deaths in the United States alone.[1]

Though the COVID-19 virus itself was novel, meaning it had never been seen in humans, the experience of a deadly infectious disease spanning the globe is not novel. Just over a century ago the Spanish Flu of 1918 infected 500,000,000 people, killing an estimated 50,000,000 worldwide.[2] More recently, in December 2013, the Ebola Virus Disease (EVD) surfaced in rural parts of Guinea and spread into Liberia, Sierra Leone, Nigeria, Mali, and Senegal in what would become known as the West Africa Ebola Epidemic. Two and a half years later the EVD outbreak was declared over, but not before 28,600 cases had been reported with more than 11,325 deaths.[3] Additionally, since the turn of the century the world has seen multiple other notable infectious disease outbreaks, including the 2002 SARS epidemic in China, the 2009 H1N1 pandemic, and the 2012 MERS outbreak in Saudi Arabia. The COVID-19 pandemic, along with the memory of past infectious disease outbreaks, has generated a renewed concern in capitals all over the world about the security risks infectious diseases create. The concern over biological threats is only reinforced when one considers the technological advancements that allow scientists, and even those with far less formal training, to manipulate infectious diseases and potentially turn them into biological weapons.

The Threat of Bioweapons

The common denominator amongst infectious disease outbreaks such as the EVD and the Spanish Flu is that they were naturally occurring. For example, in the case of the Spanish Flu, an H1N1 virus of avian origin jumped to humans and then spread worldwide as a result of World War I. While the specific origins are still in question, once the virus jumped from bird to human, the spread was rapid and infected an estimated 33% of the world's population.[4] The outbreak of COVID-19 has followed a somewhat similar path as the Spanish Flu outbreak, despite policies and vaccines designed to slow its spread, as the virus has rapidly infected hundreds of millions of people around the world.

In the case of COVID-19, it will likely take years to fully understand the impact the disease has had on society. Currently, there is still intense debate as to the origins of the disease. Some experts believe the disease escaped from a biosecurity lab in Wuhan, China,[5] but others (including the World Health Organization's international expert committee that examined the pandemic's origins) refute the lab leak theory, calling it "extremely unlikely."[6] Along with the origins of the disease, only time will tell the full impact of COVID-19 on economics, security, life in general. However, it is not too soon to tell that things could have been far worse.

Synthetic Biology & New Approaches to Bioweapons

Synthetic biology is a field of science that involves redesigning organisms by engineering them to have new properties,[7] originating during the early 20th century and making significant strides over the past few decades. Specifically, this process is done by stitching together longer stretches of DNA, including both novel & pre-existing genes from existing organisms, and inserting them into an organism's genome. Humans can also manipulate an organism's genetic code through a process called genome (or simply gene) editing. Gene editing differs from synthetic biology in that gene editing is done by making small changes to the existing genetic code in an organism while synthetic biology involves assembling an entirely new genome and inserting it into a cell or microbe. Once edited, engineered organisms can be used to find solutions to complex problems in medicine, manufacturing, and agriculture. For example, synthetic biology can be used in agriculture to create food with higher nutritional and medical value, food that has a longer shelf life, and/or food that is free of allergens that may be harmful to certain populations. Additionally, synthetic biology can be applied to microorganisms that help clean soil, water, and air pollutants. Gene editing also has positive applications to fields such as medicine, where gene-therapies are being used to treat diseases like cystic fibrosis and diabetes. While the benefits of these technologies can be plenty, like many technologies there is also the ability for synthetic biology and gene editing to be used for nefarious purposes. The same tools and techniques that can be used to manually alter genomes to cure disease or clean pollution can also be used to alter genomes to kill.

Synthetic Biology Research at NASA Ames. Source: Alexander van Dijk / Flickr. CC by SA 2.0.

The threat synthetic biology and gene editing pose to the world has been thought about since before the turn of the century. In 1997, a team of scientists within a group known as JASON met to think about the future of biological weapons (BW) and biological warfare writ large.[8] This group of accomplished scientists identified six potential threats that should be considered:

1. The development of binary weapons (weapons that are created by combining two non-lethal organisms or biological products together to produce a lethal agent).
2. The construction of designer genes.
3. The use of gene therapy as a weapon.
4. The development of viruses that can avoid the immune response of the host.
5. The use of viruses that can move between humans, insects, and animals.
6. The development of designer infectious diseases.[9]

The threats identified by this group of scientists were once considered futuristic and speculative, but the development of synthetic biology tools and techniques have made the once science fiction-esque threats a real possibility. However, what is perhaps more alarming than the threats themselves is the rapidly diminishing barriers to entry in the world of synthetic biology. For example, one of the first and great breakthroughs involving the use of synthetic biology came in 2002 when a team of researchers at the State University of New York - Stony Brook was able to chemically synthesize the entire poliovirus genome.[10] Fully synthesizing the poliovirus genome took a highly accomplished and well-equipped team of scientists years to achieve. However, today the playbook the scientists used is freely available, and technological advancements in the field of synthetic biology have made this once incredible feat far more attainable by far more people with far less training.

Another example of the diminishing barriers to entry in synthetic biology is the International Genetically Engineered Machine (iGEM) competition. The iGEM competition, which includes almost 6,000 people every summer, "gives students the opportunity to push the boundaries of synthetic biology by tackling everyday issues facing the world."[11] At the core of iGEM is a positive mission—one that seeks to advance the peaceful uses of synthetic biology. However, advances in synthetic biology have allowed undergraduate and high school students to complete projects that match the sophistication of projects previously only able to be done by highly trained scientists in well-equipped labs just a decade ago.[12] For example, in 2017 a Lithuanian team developed a tool to improve the rate of inheritance of genetically altered sequences throughout generations of microbes.[13] While this iGEM winning tool can be used for peaceful, productive purposes, it can also be used to build BW by quickly altering the genomes of a weapons-starting material.[14]

Converging Threats: Biological Weapons and Terrorism

Advances in synthetic biology have made the ability to develop weapons of mass destruction (WMD) far easier than it was decades ago. As creating BW has become increasingly easier, it has exacerbated pre-existing threats to U.S. national security, such as those posed by violent extremist organizations (VEOs) like al-Qaeda. Changes in the ease of acquisition, coupled with the desire to execute mass casualty attacks by some VEOs, make the prospects of a VEO acquiring and using a genetically engineered biological weapon far more likely.

Al-Qaeda's interests in carrying out mass casualty attacks on its enemies is evident by the attacks on the U.S. on September 11, 2001. In the case of 9/11, al-Qaeda chose to use hijacked airplanes as a means to execute a mass casualty attack on the United States. While hijacked airplanes led to a devastating attack, the group has also stated a desire to acquire WMD for use in a mass causality attack. As early as 1998, al-Qaeda founder Osama bin Laden stated it was his "religious duty" to acquire WMD, which would be used for a mass casualty attack, and repeatedly issued statements that provided a rationale and justification for their use.[15] Much of the focus on countering WMD terrorism has focused on preventing VEOs from acquiring and using nuclear or radiological devices, as the detonation of even a crude nuclear weapon or dirty bomb would have monumental consequences. However, due to advances in synthetic biology and gene editing, it is far more likely that a VEO could acquire and release a BW—an event likely to have similar societal consequence to the detonation of a radiological or nuclear device.

Converging Threats: Infectious Disease & Human Behavior

No matter what health and safety measures are put into place by local, national, or federal governments, they can only be as effective as the population's willingness to adhere to them. When it comes to fighting infectious disease outbreaks, one of the largest challenges governments face is vaccine hesitancy and the wider anti-vaccination (anti-vax) movement. Additionally, if the population disagrees with the health and safety policies being put into place by governments, disgruntled citizens could turn to violence or terrorism. The human element of biosecurity has been one of the prominent features of the fight against COVID-19, especially in the United States.

Vaccine hesitancy is a phenomenon in which individuals delay acceptance of or refuse to be immunized from various infectious diseases despite availability of vaccine services.[16] This phenomenon and the relative prominence of the anti-vax movement writ large have played a major part in hampering the fight against COVID-19, despite the effectiveness of the COVID-19 vaccines available.

The first vaccination against COVID-19 approved for emergency use by the U.S. Food and Drug Administration (FDA) was the Pfizer-BioNTech on December 11, 2020. The vaccine was approved for use in individuals 16 and older initially, and the FDA expanded the emergency use authorization to include children ages 12-15 in May 2021 before receiving full approval from the FDA on August 23, 2021.[17] In the months following Pfizer-BioNTech's breakthrough, other pharmaceutical companies, such as Moderna, Astrazeneca, Johnson & Johnson/Janssen (J&J), developed and deployed vaccines nationally and internationally. While the AstraZeneca vaccine isn't approved for use in the U.S., the other three performed quite well in clinical trials.

Anti-vaccine graffiti in Italy during the COVID-19 pandemic. Source: Mænsard Vokser via wikimedia commons. CC by SA 4.0.

Despite vaccines that are both fully vetted and approved for emergency use by the FDA after performing remarkably well in clinical trials, vaccine hesitancy has become a major challenge towards achieving herd immunity, stopping the spread of COVID-19, and returning to "normal." What makes the challenge of vaccine hesitancy so difficult is that the hesitancy stems from a longstanding mistrust in technical, health, and government institutions in the U.S. (and Europe).[18] According to researchers at the University of Michigan's Ford School of Public Policy, "Communities question whether their governments, and scientific, technological and medical institutions, really represent their needs and priorities. Long legacies of mistreatment of marginalized communities further fuels this mistrust."[19]

In 2022, vaccine hesitancy is further compounded by the ability for misinformation to be rapidly shared across social media networks like Twitter, Facebook, and Instagram. For example, Instagram's leadership vowed to fight the spread of misinformation about vaccines and COVID-19 on its platform, but the efforts have seen mixed results. The popular photo-sharing social media platform has added links to a COVID-19 Information Center (that has information about vaccines, state health websites, facts about COVID-19, and related pages) to posts the reference COVID-19, but users have still been able to proliferate anti-vax posts that include falsehoods about vaccines, COVID-19, and links between vaccines and autism.[20] A hesitancy to get vaccinated, along with the ability to rapidly share false or misleading public health information, has created a challenging environment for containing the spread of COVID-19. In the future, if an infectious disease outbreak or genetically engineered BW is more lethal than COVID-19, the anti-vax movement and social media falsehoods could lead to far more fatalities as a designer disease will likely carry a much higher fatality rate while spready similarly as quick.

In addition to the anti-vax movement and vaccine hesitancy as a whole, other aspects of human behavior, especially religious practices related to death, play a role in the spread of infectious disease. During the 2014 EVD outbreak in West Africa, the virus ran rampant for numerous reasons including its emergence in highly populated urban areas, low-quality health facilities, and a lack of awareness amongst the affected communities. However, on top of those three key drivers, researchers and the WHO found that some traditional and religious practices followed in West African communities had "tremendous negative effects on the spreading of the disease" and led to nearly 60% of all EVD disease transmission in Guinea.[21] Traditional and religious practices that can account for virus spread include a misunderstanding of the causation of disease and death, use of traditional and spiritual healing, and burial practices such as washing and cleaning the body before it is laid to rest.[22]

Improving National & International Biosecurity

The COVID-19 pandemic has made it abundantly clear that the outbreak of infectious disease, even a naturally occurring disease with a relatively low fatality rate, poses severe health, economic, and security risks to states worldwide as the disease has been highly transmissible, leading to millions of deaths. The COVID-19 pandemic has also made it very clear that biosecurity cannot be handled on a strictly national or local level, but rather full, transparent, international cooperation is necessary. As the world begins to return to "normal," Washington should take several steps to ensure future infectious disease outbreaks are not nearly as disruptive as COVID-19 has been.

Revamp International Biosecurity Measures

The first and most important thing the U.S. can do to improve biosecurity in the future is to lead the international push to revamp biosecurity. As COVID-19 has impacted every corner of the globe, interest in protecting against future pandemics should be of interest in capitals all over the world. Leading the charge on revamping international biosecurity measures should be of special interest to the Biden administration given its own stated national security goals. In the March 2021 Interim National Security Strategic Guidance released by the Biden White House, one of the highest priorities is protecting the U.S. from transnational issues that do not respect borders and do not carry passports, such as infectious disease.[23] Additionally, one of the avenues the Biden White House has identified to achieve its national security goals is to reengage the international community by recommitting to U.S. alliances and partnerships, working in coordination with international organizations and institutions to tackle shared challenges, such as COVID-19, and working to build partnerships around the world.[24] Finally, one of the hallmarks of the Biden administration's national security posture has been continuing the Trump administration's focus on competing with China. By leading the effort to revamp international biosecurity, the U.S. can beat China to the punch, help ensure the U.S. and world remain safe from biological threats and reestablish itself as a responsible and reliable actor in the international community.

Leading the charge on an international biosecurity overhaul can help beat China to the punch because Beijing has been laying the groundwork to take a leading role on biosecurity, notably by using the United Nations. Through the UN, China has declared a commitment to "strengthening global biosecurity governance" and to "dealing with the . . . threats posed by biological warfare and bioterrorism."[25] The U.S. leading the charge on international biosecurity should also be the top priority in Washington's efforts to overhaul biosecurity because it can be parlayed into other strategic (inter)national security objectives, especially related to WMD. When the Biological Weapons Convention (BWC) was enacted in 1975, one of the major holes in the landmark agreement was the lack of a verification mechanism, meaning countries were unaware of who was actually complying with the terms established in the BWC. After the Soviet Union collapsed in the 1990s, the international community sought to remedy the verification hole in the BWC by enacting a protocol that would establish procedures for randomly selected site visits and allow for rapid means to investigate biological weapons development, stockpiling, and/or use. However, in 2001 the U.S. pulled out of a United Nations group that was drafting the protocol, meaning the verification provisions meant to bolster the

BWC were never enacted into international law. At the time, the U.S. ambassador to the ad hoc group drafting the protocol stated the U.S. could not support the protocol because the text would "do little" to deter BW proliferation and it would not improve Washington's ability to verify BWC compliance.[26] China has used Washington's opposition to biosecurity measures it sees as ineffective, demonstrated by the U.S. killing the 2001 BWC verification protocol attempt, as an excuse to not engage on arms control topics writ large. For example, when the Trump administration invited China to partake in bilateral talks on nuclear weapons arms control, Beijing refused, declaring the idea "absurd" because "the United States stood singly in the way of negotiations for a [BWC] protocol that includes a verification regime."[27]

In order to demonstrate international leadership on biosecurity, the U.S. can take several measures. For example, the Biden Administration could announce a series of international summits, similar to the ones the Obama administration convened on nuclear security, to address issues with biosecurity. Additionally, the U.S. could work with international institutions like the World Health Organization to ensure virology lab safety standards are consistent, and potentially verifiable, across the world. These measures should especially focus on improving safety standards and practices at the labs around the world that study the deadliest pathogens, or biosafety level 4 labs (BSL-4). Today, 23 countries around the world house 59 BSL-4 labs but those numbers are likely to increase as countries build more to better understand viruses like the one causing COVID-19.[28] What is more alarming is that of the 59 labs worldwide, only a quarter of them are in countries that score highly in a ranking of international biosafety and biosecurity measures put together by the Nuclear Threat Initiative (NTI).[29] NTI's index measures whether countries have legislation, regulation, oversight bodies, and other components of sound biorisk management.[30] Regardless of the specific avenue chosen, leading the charge on international biosecurity overhaul can help keep the U.S. safe from infectious disease outbreaks, can help reestablish the U.S. as a responsible and reliable international partner, be parlayed into other national security objectives, and can score points in the burgeoning strategic competition between Washington and Beijing.

Heads of delegation at the 2016 Nuclear Security Summit gather for photo in Washington, D.C. in April 2016 Source: US Department of State.

Establish Controls on Emerging Technology

The second thing the U.S. can do to improve biosecurity in the future is to treat potentially harmful biotechnology in a similar fashion to other dual-use goods, or goods that have both civilian and military capabilities. Export controls in the U.S. have been around since before the Declaration of Independence was signed, the first control coming when the First Continental Congress banned the export of goods to Britain. Over the years, the U.S. has continued to restrict trade with hostile countries, using mechanisms such as the Trading with the Enemy Act of 1917, designed to prevent trade with Germany and the Central Powers during World War I. Export controls have evolved over the years to restrict trade not just with certain countries deemed hostile, but with certain goods that are potentially dangerous—especially those that play a role in WMD proliferation.

Today, dual-use goods that can be harmful to U.S. national security and foreign policy are regulated by the U.S. Department of Commerce's Bureau of Industry and Security (BIS). BIS "administers U.S. laws, regulations and policies governing the export and reexport of commodities, software, and technology (collectively "items") falling under the jurisdiction of the Export Administration Regulations (EAR)" and "seeks to advance national security, foreign policy, and economic objectives by ensuring an effective export control and treaty compliance system, and promoting continued U.S. strategic technology leadership."[31] Items on the EAR are broken into nine categories, shown in the table below:

Category	Items in Category
0	Nuclear Materials Facilities & Equipment (and miscellaneous items)
1	Materials, Chemicals, Microorganisms, and Toxins
2	Materials Processing
3	Electronics Design, Development, and Production
4	Computers
5	Telecommunications and Information Security
6	Sensors and Lasers
7	Navigation and Avionics
8	Marine
9	Aerospace and Propulsion

When it comes to regulating exports on items relevant to WMD production, categories zero and one include items that can be used to develop nuclear, chemical, or biological weapons. For example, category one states that export of items, such as full face masks, filter canisters, and decontamination equipment, related to biological agents, defined as "pathogens or toxins, selected or modified (such as altering purity, shelf life, virulence, dissemination characteristics, or resistance to UV radiation) to produce casualties in humans or animals, degrade equipment or damage crops or the environment"[32] are controlled by the EAR and require special licenses to allow for exportation. However, with advances made in biology over the last 20-30 years, an individual is able to acquire and edit DNA from their smartphone. In a January 2021 podcast interview on the show *Intelligence Matters*, Dr. Ken Wickiser, a biochemist and associate dean of research at U.S. Military Academy West Point stated "You can do genetic engineering right from your phone. You can purchase DNA on the spot. At the end of the purchasing process, there's a little form to sign that says 'is this a poison, yes or no? Can this impact human health? Yes or no?' It really comes down to you as the purchaser being honest. We have this incredible capability in biology. Yet the controls haven't caught up to that yet."[33] While some BW-related items appear on the EAR and thus are controlled by the U.S. government, it is clear there is still a lot that can be done to improve controls on acquiring BW-related material and thus, raising the barrier to entry for creating biological weapons.

Maintain National Preparedness

The third thing the U.S. can do to improve biosecurity in the future is to ensure adequate levels of preparedness for future biological threats. Particularly, the U.S. can ensure adequate levels of supplies are stored in the Strategic National Stockpile (SNS). The SNS, an initiative within the U.S. Department of Health & Human Services, "has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (terrorist attack, outbreak, earthquake) severe enough to cause local supplies to run out."[34] Should a biological attack happen, the SNS reserves include numerous products and supplies needed to help combat the threat, including personal protective equipment (PPE) like gowns, N95 respirators, and various models of ventilators. The COVID-19 pandemic illustrated the importance of having an adequately stocked SNS to respond to a biological threat.

A shipment of personal protective equipment received from the Strategic National Stockpile March 31, 2020 to be sorted and distributed to the 46 counties in the state in support of the COVID-19 response efforts. Source: South Carolina National Guard.

When the pandemic first hit the U.S. in early 2020, it became evident quickly that the country was not prepared for such a threat as the SNS stockpiles were previously depleted and hadn't been restocked. The SNS has been used 13 times since its creation, including to respond to events such as the terrorist attacks of September 11, 2001, the 2001 anthrax attacks, and hurricanes Katrina, Rita, Gustav, and Ike from 2005-2008.[35] After SNS usage led to dwindled supply, the SNS would typically be replenished, except during the Obama administration. During the Obama administration several instances required the use of the SNS including the 2009 H1N1 pandemic response, several hurricanes and floods, the 2014 Ebola outbreak, and the 2016 outbreak of zika virus.[36] After these occurrences, there was no serious effort made by the Obama administration to replenish the SNS. While there was money allocated to restock the SNS, experts say, "With limited resources, officials in charge of the stockpile tend to focus on buying lifesaving drugs from small biotechnology firms that would, in the absence of a government buyer, have no other market for their products. Masks and other protective equipment are in normal times widely available and thus may not have been prioritized for purchase."[37] While masks and other PPE may be more widely available during non-crisis times, the COVID-19 pandemic showed that supply diminishes quickly when demand is high. For example, mask prices purchased through platforms like Amazon rose rapidly, with prices of some masks hitting more than $200 for a pack of ten (an increase from $18.20 for the same 10 pack of N95 respirators a month prior).[38] Ensuring the SNS is adequately supplied will contribute to increased resilience in the face of future biological threats.

Centralizing Community Response

The fourth thing the U.S. can do to improve biosecurity is develop community response plans at the local and state level. When the COVID-19 pandemic first hit the world and the PPE shortage was realized, technological advances, such as 3D printing, allowed for everyday members of the community and groups to act independently to help stock hospitals and medical staff in need of PPE. For example, a Madrid-based organization, Ayudame3D, was best known for using 3D printings capabilities to print prosthetic arms for those in need. However, when COVID-19 hit, the organization shifted its focus to printing plastic face shields and was able to donate 20,000 plastic face shields.[39] In another example, a 17-year-old high school student in Hong Kong organized a drive that raised over $5,000 for economically disadvantaged families and collected hundreds of 3D-printed face shields to donate to hospitals across Hong Kong.[40] The COVID-19 response showed the power of community action in responding to biological threats, and the U.S. would be keen to learn from this to help prepare for future biological challenges. However, in order to maximize the effectiveness of community action, the U.S. should develop a government approved, publicly accessible database of 3D printable parts or other community-producible supplies for emergency situations. Having an approved database of parts and supplies can ensure optimization, both in terms of speed and ease of production, as well as establish minimum safety requirements for donations to ensure resources needed, which can become scarce quickly, are used efficiently. On top of having a database that establishes baseline specs for 3D printed material, having a regularly updated database for national and local needs can ensure community action helps meet the needs of the country.

Conclusion

As technological advances continue, the threat posed by biological weapons will grow with it. What once took the work of a team of well-trained, well-equipped scientists can now be done much quicker by those with much less formal training, such as high school or undergraduate students. The COVID-19 pandemic showed the world it was wildly unprepared for a biological threat, and COVID-19 is far less lethal than an engineered weapon could be. In order to keep the U.S. safe from future biological threats, Washington can take several steps at the international and national levels to reduce the threat of infectious disease outbreak, especially those engineered for malicious purposes.

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